

Applicant: Odell et al.
Application Serial No.: 09/897,309
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Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 - 18 (previously canceled)

Claim 19 (currently amended): A method of producing prefillable glass syringe barrel assemblies comprising the steps of:

forming a plurality of clean syringe barrels in a glass forming device for shaping a cylindrical glass tube into syringe barrels having a first open end for receiving a syringe plunger and a second open end for discharging contents from said syringe barrels;

annealing said glass syringe barrels at a temperature of at least 500°C; then,

immediately transferring said syringe barrels to at least one housing assembly for maintaining a predetermined cleanliness level, without any sterilization between said annealing and said transferring steps.

Claim 20 (previously presented): The method of claim 19, further comprising coupling at least one syringe component to said syringe barrels to form a plurality of syringe barrel assemblies,

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forming an array of syringe barrel assemblies in said at least one housing assembly, placing said array in a container and closing said container.

Claim 21 (original): The method of claim 20, wherein said forming step comprises supplying a cylindrical glass tube to said forming device and heating a first end of said glass tube to a temperature whereby said glass tube is pliable and forming a flange about said first open end and heating a second end of said glass tube to a temperature whereby said glass tube is pliable and forming a tip at said second end.

Claim 22 (original): The method of claim 21, wherein said first and second ends of said glass tube are heated to a temperature of about 760°C to 1100°C.

Claim 23 (original): The method of claim 21, further comprising annealing said syringe barrels by heating to at least about 560°C.

Claim 24 (original): The method of claim 20, further comprising the step of cleaning said syringe barrels in said at least one housing assembly prior to forming said array.

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Claim 25 (original): The method of claim 24, wherein said cleaning step comprises directing a stream of filtered, ionized air onto said syringe barrels to remove particulates from surfaces thereof.

Claim 26 (original): The method of claim 20, wherein said at least one housing assembly includes an air blower and a HEPA filter coupled to said air blower to filter air entering said housing assembly and maintain a cleanliness level of about Class 100.

Claim 27 (original): The method of claim 19, wherein said at least one housing assembly is maintained at a positive internal pressure to prevent unfiltered air from entering said housing assembly.

Claim 28 (original): The method of claim 20, further comprising transferring said syringe barrels to a second housing assembly and applying a coating of a lubricant to an inner surface of said syringe barrels prior to forming said array.

Claim 29 (original): The method of claim 28, further comprising transferring said syringe barrels to a third housing assembly and packaging said syringe barrels while in said third housing assembly.

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Claims 30-32 (previously canceled)

Claim 33 (currently amended): A method of producing a filled syringe comprising the steps of:

forming a plastic syringe barrel in an injection molding machine, said syringe barrel having a cylindrical side wall, an open proximal receiving end and a frustoconically shaped outlet nozzle at its distal end;

transferring said syringe barrel, without any additional cleaning or sterilization, into an environmentally controlled area to maintain a predetermined cleanliness level;

directing a stream of filtered air toward said syringe barrel in said environmentally controlled area to remove particles from surfaces thereof to clean said syringe barrel;

delivering a tip cap to said environmentally controlled area;

air ~~cleaning~~ washing said tip cap in said environmentally controlled area;

assembling said tip cap to said outlet nozzle of said syringe barrel to close said outlet nozzle;

filling said syringe barrel with a substance through its open proximal end;

delivering a stopper to said environmentally controlled area;

inserting said stopper into said open proximal end of said barrel to form a prefilled syringe; and

removing said prefilled syringe from said environmentally controlled area.

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Claim 34 (original): The method of claim 33, further including the step of packaging said prefilled syringe.

Claim 35 (original): The method of claim 33, further including the step of sterilizing said prefilled syringe.

Claim 36 (original): The method of claim 33, further including the steps of sterilizing said prefilled syringe followed by the step of packaging said prefilled syringe.

Claim 37 (original): A method of producing a filled syringe comprising the steps of:

forming a plastic syringe barrel in an injection molding machine, said syringe barrel having a cylindrical side wall, an open proximal receiving end and a frustoconically shaped outlet nozzle at its distal end;

transferring said syringe barrel, without any additional cleaning or sterilization, into an environmentally controlled area to maintain a predetermined cleanliness level;

directing a stream of filtered air toward said syringe barrel in said environmentally controlled area to remove particles from surfaces thereof to clean said syringe barrel;

delivering a stopper in said environmentally controlled area;

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inserting said stopper into said open proximal end of said syringe barrel to close said proximal end;

filling said syringe barrel with a substance through its outlet nozzle;

delivering a tip cap to said environmentally controlled area;

air ~~eleaning~~ washing said tip cap in said environmentally controlled area;

assembling said tip cap to said outlet nozzle of said syringe barrel to form a prefilled syringe; and

removing said prefilled syringe from said environmentally controlled area.

Claim 38 (previously presented): The method of claim 37, further including the step of packaging said prefilled syringe.

Claim 39 (previously presented): The method of claim 37, further including the step of sterilizing said prefilled syringe.

Claim 40 (previously presented): The method of claim 37, further including the steps of sterilizing said prefilled syringe followed by the step of packaging said prefilled syringe.